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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,248	03/29/2004	Alex J. Harvey	AVI-027N	2313

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AVIGENICS, INC.  
111 RIVERBEND ROAD  
ATHENS, GA 30605

EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/812,248

Applicant(s)

HARVEY ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method of producing an integrated transgene in an avian cell by introducing a nucleic acid comprising a non-lethal marker gene into an avian cell by electroporating, and allowing the cell to undergo cellular division, thereby producing an integrated transgene in an avian cell, classified in class 435, subclass 461.
- II. Claims 11-18, drawn to a method of producing a transgenic avian by injecting an electroporated avian cell comprising a coding sequence for a light chain or heavy chain of an antibody into an avian embryo, classified in class 800, subclass 21.
- III. Claims 11-16, 19 and 20, drawn to a method of producing a transgenic avian by injecting an electroporated avian cell comprising a coding sequence for an interferon into an avian embryo, classified in class 800, subclass 21.
- IV. Claims 21-32, drawn to a method of screening for nucleic acid integration in a cellular genome comprising transforming a nucleic acid comprising a marker into a recipient avian cell and determining if the nucleic is present in an equal copy number in cells of a colony produced by the recipient

avian cell, thereby screening for nucleic acid integration in a cellular genome, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination (Group I, transfecting avian cells) has utility by itself. The subcombination (Group I) has separate utility such as transfecting avian cells to make them immortal, or to express exogenous proteins in avian cells used in *in vitro* assays.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination (Group I, transfecting avian cells) has utility by itself. The subcombination (Group I) has separate utility such as transfecting avian cells to make them immortal, or to express exogenous proteins in avian cells used in *in vitro* assays.

Groups I and IV are patentably distinct because the method of Group I is used to transfect avian cells while the method of Group IV is used to determine whether a transgene has integrated into the genome of an avian cell after transfection. The protocols and reagents required to perform the methods of Groups I and IV are materially distinct and separate. The methods are not disclosed as being used together. The burden required to search and examine both Groups I and IV together would be undue.

Groups II and III are patentably distinct because the method of Group II is used to make a transgenic avian overexpressing antibodies while the method of Group III is used to make a transgenic avian overexpressing interferon. Overexpressing antibodies in transgenic avians has a different function than overexpressing interferon. The constructs required to perform the methods of Groups II and III are materially distinct and separate. The methods are not disclosed as being used together. The burden required to search and examine both Groups II and III together would be undue.

Groups II and IV are patentably distinct because the method of Group II is used to make a transgenic avian while the method of Group IV is used to determine whether a transgene has integrated into the genome of an avian cell after transfection. The protocols and reagents required to perform the methods of Groups II and IV are materially distinct and separate. The methods are not disclosed as being used together. The burden required to search and examine both Groups II and IV together would be undue.

Groups III and IV are patentably distinct because the method of Group III is used to make a transgenic avian while the method of Group IV is used to determine whether a transgene has integrated into the genome of an avian cell after transfection. The protocols and reagents required to perform the methods of Groups III and IV are materially distinct and separate. The methods are not disclosed as being used together. The burden required to search and examine both Groups III and IV together would be undue.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the

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office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of vertical strokes followed by a long horizontal line extending to the right.

**MICHAEL WILSON**  
**PRIMARY EXAMINER**